International Dairy Foods Association
Milk Industry Foundation
National Cheese Institute
International Ice Cream Association

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Michael Landa
Deputy Director for Regulatory Affairs
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

Dear Mr. Landa:

I want to thank you very much for meeting with the International Dairy Foods Association (IDFA), our constituent organization, the International Ice Cream Association (IICA)) and two of our member companies recently on our petition for a stay of effective date for the trans fat labeling rule. That stay, if granted, would apply to small businesses that make ice cream and frozen dessert products (hereinafter "ice cream") and meet the criteria specified in the petition. We very much appreciate the time and attention that you and your colleagues are giving to this issue, and your willingness to consider our request.

Based on the discussion at that meeting, we wanted to follow-up to address more specifically two questions that were raised by your staff: (1) to what extent granting our petition might create a broader precedent, thereby inviting others in the food industry to come to you with additional requests for a stay of effective date; and (2) why the ice cream industry did not raise these issues earlier with the agency. Let me take this opportunity to address both of these questions.

1. Limited Precedent for Other Segments of the Food Industry

As described in our petition, we believe that the unique set of factual circumstances surrounding our request make this very small group of ice cream manufacturers well outside the norm within the food industry. This is due to the confluence of multiple factors, including: (a) our request would apply to a tiny fraction of small businesses; (b) these companies have a disproportionate number of stock-keeping-units (SKUs) per company; (c) we submitted data on the actual added costs that would be incurred if an extension were not given; (d) the companies are proceeding as fast as they can, but due to limited capacity simply cannot meet the current deadline; and (e) most importantly, over 90 percent of these products would contain 0 grams of trans fat, and the remainder would contain only 0.5 grams. Let me elaborate:

a. Tiny Fraction of Small Businesses: The first factor is that IDFA's petition is submitted solely on behalf of approximately 30 small businesses in this product category. They all meet the Small Business Administration (SBA) definition of fewer than 500 employees. Moreover, the fact that there are only approximately 30 of them shows the very limited applicability of the requested stay.

b. Disproportionate Number of SKU's: As stated in our petition, these companies have a disproportionately large number of SKU's, averaging over 200 per company (ranging from 23 to 500). This is due to the combination of the many flavors offered for each brand; the number of sizes per flavor; and the multiple numbers of private label distributors that these small ice cream manufacturers supply. There are very few other segments of the food industry that have so many labels to change.

c. Data on Costs Supplied to FDA: A third distinguishing feature of these small ice cream manufacturers is they took the time to collect data on what added costs would be incurred from discarding obsolete labeling if an extension were not given. The high amount of obsolete labeling is due to the fact that labeling suppliers have minimum order requirements, which for small companies could take a long time to use up. As summarized in the attachment to our petition, these added costs would average $85,000.00 per company, or $2,565,000.00 for all 30 companies combined. This is a high cost for small businesses to absorb where, as here, there is no corresponding public health benefit. Moreover, these are just the added costs due to discarding old labels, and are over and above the costs of the labeling changes themselves.

d. Limited Capacity to Meet Existing Deadline, Despite Best Efforts. As described at our meeting, these companies are working hard to meet the existing deadline, but due to their limited capacity they simply will not be able to achieve full compliance by January 1, 2006, despite their best efforts. The fact that these companies are moving ahead as fast as they can—and not "waiting" for a ruling from the FDA—demonstrates their desire to achieve compliance, and provides another factor that could distinguish them from other potential industry petitioners.

e. These Products Contain 0 grams of Trans Fat, or Very Close To It. Notwithstanding all of the above, the most important distinguishing characteristic of our petition is that an estimated 90 percent of the products involved would contain 0 grams trans fat under the regulation; of the remainder, we know of no product that would be labeled above 0.5 grams of trans fat, the lowest level above "zero" according to the regulation. This means that, were FDA to grant an extension, there would be virtually no negative public health impact because consumers would not unknowingly be exposed to products with high levels of trans fat.

Taken together, these factors present a unique factual scenario that would be very difficult -- and highly unlikely -- for other industry segments to replicate. Although we cannot know for certain, we know of no other industry segment where a tiny fraction of small companies have a highly disproportionate number of labels to change, collected data documenting the added costs from discarding old labels, are making best efforts to achieve compliance subject only to their inherently limited capacity, and—most importantly--where the final product, once labeled, will list 0 grams of trans fat 90 percent of the time or, at most, 0.5 grams. Accordingly, granting the requested relief to IDFA, based on this record, would not easily open the door for other, equally well-supported petitions to follow.

2. Timing of Request to FDA

Given that the FDA published the final rule in July 2003, it is reasonable to ask why the industry did not submit its petition until December 2004. The answer is that it took this small segment of the industry that long to recognize the problem, based on intermediate steps outside of their control.

The first such step is that these small manufacturers did not have the capability and resources to determine, for themselves, the level of trans fatty acids in milk fat. To assist them, IDFA undertook a research project to obtain this data. The current scientific literature provides very few references on the level of trans fatty acids in milk fat, and did not have detailed information on the level of conjugated milk fat which under FDA's regulations is deducted from the declared labeling value. IDFA determined it as necessary to obtain contemporary nutrient analysis on the amount of trans fat in milk fat. Most dairy and ice cream manufactures choose to use IDFA nutrient data rather than initiating testing of their individual milk ingredients or finished products. This project began in August 2003, shortly after the final rule was released, but was not completed until June 15, 2004. This ten month project initially undertook fatty acid analysis to determine if trans fat levels in milk were altered when raw milk was further processed into cream, butter and anhydrous milk fat. Results determined that there was no significant change in trans fat with processing of milk into other concentrated fat products.

The project was then expanded to obtain representative milk samples across the U.S. in regions where milk is commonly produced. Samples were tested for fatty acid profile and statistical analysis was undertaken to determine the weight mean and predicted value for the level of trans fat in milk. Although this industry data is not an official nutrient database as defined by FDA, it is being utilized by most dairy and ice cream firms that utilize typical U.S. milk and milk fat products as ingredients. This nutrient analysis project is similar to a comprehensive data the dairy industry gathered during the implementation on the Nutrition Labeling Education Act (NLEA). At that time, FDA reviewed our methods, analysis and data and provided a response letter to IDFA stating that the database, though not approved by FDA, could appropriately be used for nutrient labeling purposes.

Once the amount of trans fat in milk fat was available, the ice cream manufacturers then needed to obtain information from their many ingredient suppliers of the amount of trans fat in those ingredients. However, these ingredient suppliers were slower than

anticipated in providing this information because, as we now understand in hindsight, they were in the process of reformulating their ingredients, to the extent feasible, to reduce or eliminate trans fat content. Such reformulation is fully consistent with Agency goals and the public interest, but it placed these small manufacturers at a distinct disadvantage.

Finally, now that much of this data has been made available to manufacturers, these small ice cream manufacturers again find themselves at the "low end of the food chain" when it comes to getting their labels reformatted and reprinted. The limited number of packaging firms are naturally going to address the needs of their largest customers first, and so the progress of small ice cream manufacturers label changes are going to be much slower than larger companies.

In summary, while IDFA regrets that it was not able to petition FDA earlier, the timing for submission of the petition was based on when these small manufacturers recognized they had a serious problem with meeting the compliance date, and that the timing was due to legitimate reasons outside of their own control.

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I again want to thank you for your time and consideration to this petition. Our members will continue to diligently work towards achieving full compliance of the trans fat labeling rule as quickly as their capacity allows. We believe our petition has merit, that it is based on an unusual confluence of factors, and that granting it would not create an unwanted precedent for the FDA. We regret that we were not in a position to raise this issue with you earlier, but we did so as soon as it was apparent we had a serious problem.

We would be pleased to answer any additional questions you may have.

Sincerely yours,

Clay Hough
Senior Vice President and General Counsel
International Dairy Food Association

cc: Barbara Schneeman, Ph.D.
Director, ONPLDS

Kathleen Ellwood, Ph.D.
Director, Nutrition Programs and Labeling
ONPLDS

Leslye Fraser, Director
Regulations and Policy